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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,318	11/07/2001	Erik Leonard Hoffman	05032-00011	4521

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EXAMINER
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COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3732

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DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/037,318

Applicant(s)

HOFFMAN, ERIK LEONARD

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-26 are directed to non-statutory subject matter.

Claims 16-26 positively recite the combination of the fastening device and bone.

As such, the claims are considered to claim a human being which is considered to be non-statutory subject matter. A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 10, 11, 13, 14, 34-36, 38, 43, 44, 46, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Yapp (0 099 167; cited by Applicant).

Yapp discloses a fastening element 12 comprising a supporting element 24, a hollow pin 13, and fixing means 28. (See Figs. 1-7.) The supporting element has a bottom surface 22 that abuts sawn-off bone 42 and a top surface 26 that is flat and parallel to the bottom surface. The supporting element is thus plate shaped and also extends on at least two sides beyond an outer longitudinal edge of the pin (see Figs. 3 and 4). The supporting element further comprises a coupling element 32 on a side remote from the pin. The pin extends from the supporting element into bone 42. The pin is at an angle with respect to a main surface of the supporting element (see Fig. 4). The pin is not symmetrical with respect to the longitudinal axis but rather is rectangular in cross section (see Figs. 3 and 4 and page 5, lines 2-5). The pin has a finish, i.e. porous bone contact surfaces 20, 22, to promote bone ingrowth into the hollow pin (see Figs. 1, 4, and 7 and page 3, lines 23-26). After the bone ingrowth has occurred, both the outside and inside surfaces of the pin are in contact with bone tissue. The fixing means fixes the fastening element in position wherein the pin extends into bone. The fixing means comprises a screw 28 that screws into the pin from the side remote from the supporting element. The screw adjusts the tension of the fixing means.

Claims 27, 28, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincent et al. (5,007,935).

Vincent discloses a tool comprising a template 73 having a hole pattern 87 corresponding to the circumference of a pin 81,83 and including a central opening 82. The holes extend in a direction that is parallel to the longitudinal axis of the pin (see Fig. 3).

Claims 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Masini (5,571,203).

Masini discloses a method of sawing a femur on a cut line 230 to create an abutment surface that extends at right angles to a load axis of a joint (see Figs. 2-4 and 6 and col. 6, lines 35-65). The hollow pin 312 of a fastening element 442 is driven into a hole formed in the bone such that a supporting element 226, to which the pin is attached, abuts the abutment surface. The supporting element has a bottom surface 228 and a top surface that is flat at least at its periphery and parallel to the bottom surface. The pin is driven in at a 90 degree angle with respect to the surface. The device is fixed from a remote side through cortical bone by a pin 250 introduced through cortical bone 214 and fixed to the device at a connection 234.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 7-9, 12, 15, 37, 40-42, 45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp (0 099 167; cited by Applicant).

Yapp discloses the claimed invention except for the fixing means comprising a wire element or the fixing means comprising two or more screws. The use of wire elements and/or multiple screws instead of a single screw is a functionally equivalent

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means of retaining a joint coupling element, known in the art (see, e.g. Lin [5,376,126; cited by applicant]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute cables and/or multiple screws for a single screw, since doing so involves nothing more than the substitution of functionally equivalent retaining means known in the art. With regard to claims 7-9 and 40-42, it also would have been obvious to form the pin at an angle less than 125 degrees, between 125 degrees and 145 degrees, or at an angle greater than 145 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to claims 12 and 45, it also would have been obvious to form the device from a shape-memory metal since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 6 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp (0 099 167; cited by Applicant) in view of Grimes (4,795,473).

Yapp discloses the claimed invention except for the coupling element being offset with respect to the longitudinal axis of the pin. Grimes discloses a similar device 1 having a coupling element 25 offset with respect to the longitudinal axis of the pin by angle A2 in order to load the femur in a manner similar to the original femoral head and neck and thereby minimize deterioration of the femur (see Grimes, Fig. 1; col. 4, lines 35-41; and col. 2, lines 25-30). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to provide the fastening element of Yapp with an offset coupling element, in view of Grimes, in order to load the femur in a manner similar to the original femoral head and neck and thereby minimize deterioration of the femur.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masini (5,571,203) in view of Tager et al. (5,330,536).

Masini discloses the claimed invention (see Masini, Fig. 6) except for the pin being hollow such that bone contacts the both the inside and the outside of the pin. Tager et al. disclose a similar device having a hollow pin and openings into the hollow pin to enable the pin to be filled with bony ingrowth to achieve a secure and long-lasting anchoring of the pin in the bone (see Figs. 1 and 2 and col. 2, lines 11-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device used in the method of Masini with a hollow pin and openings, in view of Tager et al., in order to enable the pin to be filled with bony ingrowth to achieve a secure and long-lasting anchoring of the pin in the bone.

### ***Response to Arguments***

Applicant's arguments filed 14 January 2004, with respect to claims 16-26 rejected under 35 USC 101 have been fully considered but they are not persuasive.

In response to applicant's argument that claims 16-26 do not recite non-statutory subject matter, it is noted that the claim does not specify that the assembly is an "ex-vivo" assembly of bone and a fastening element. Instead, the claim merely recites

bone. Furthermore, when read in light of the specification, that bone is understood to be a femur of a living human. At page 3, line 21 - page 4, line 15 of the specification, Applicant describes that the pin is driven into *the* bone (referring to the assembly of bone and a fastening element for an implant) and that the supporting element is supported by the *calcar femorale* of *the* bone. Thus, *the* bone referred to is the femur. Furthermore, if this were not so, it is unclear how an "ex-vivo" bone could produce bone ingrowth into the pin (page 4, lines 3-4).

Applicant's arguments with respect to Vincent et al. have been considered but are moot in view of the new ground(s) of rejection.

It is noted that Applicant did not separately address the template tool of Vincent et al. Furthermore, regarding the intended use of the tool, i.e. "a tool *for* fitting a fastening element according to claim 1 or claim 34," it is noted that if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Here, the template is capable of being held or secured in a desired position and orientation against the bone while holes are drilled or pins are inserted therethrough.

### ***Conclusion***

Applicant's amendment making the pin hollow to have an inside and outside bone contact surface and adding new claims 34-56 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**



See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock  
17 April 2004



KEVIN SHAVER  
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